DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
850 Third Avenue
Brooklyn, NY 11232

m2474

WARNING LETTER

March 19, 1999

REF: NYK-1999-38

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roger Pagano
Assistant Administrator
Brooklyn Medical Group, P.C.
153 Pierrepont Street
Brooklyn, NY 11201

Facility ID: 1849450004

Dear Mr. Pagano:

We are writing to you because on February 22, 1999, your facility was inspected by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

> ***The interpreting physician, [redacted] M.D., did not meet the requirement of being board certified by an FDA-recognized board or having the alternative of two months training in the interpretation of mammograms.***

The specific problem above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions

include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you after the close of the inspection. This Level 2 finding is:

The x-ray system in room 2 is not accredited.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

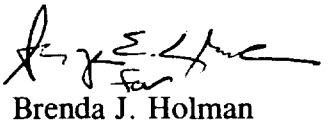
- the specific steps you have taken to **correct** all of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations; and
- sample records that demonstrate correction.

Please submit your response to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232, Tel. (718) 340-7000, ext. 5142.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/dmqrp.html.

If you have questions about mammography facility requirements in general, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely yours,



Brenda J. Holman
District Director